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09/672,074	09/28/2000	Philip Henry Coelho	30111-pa	4198

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,074

Applicant(s)

COELHO ET AL.

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11-13, 19-22, 28-32 and 45-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 11-13, 28-32 and 45-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 56, 57 and 60-67 is/are rejected.
- 7) ☒ Claim(s) 58 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Response to Appeal Brief

1. In view of the appeal brief filed on 5-28-2003 and the advice of the examiner's appeal conferees, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Election/Restrictions

2. Claims 1-5, 11-13, 28-32, and 45-54 remain non-elected and withdrawn from further consideration.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 60 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Medwed.

5. Medwed discloses a forming a container which comprises forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface, and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface (fig. 2 as an example). A sheet is placed over said mold and is caused to conform to the mold and retains having the configuration of the mold (fig. 1 and 4). The conformed sheet is removed from the mold and the first sheet is closed with another sheet parallel to the planar surface (fig. 1 again). Moreover, the container constructed by Medwed would also read on the claim language drawn to the resistance to brittleness and deformation because any container made with a thermoplastic material will have some degree of flexibility with brittleness or resistance to deformation. Although Medwed doesn't specify anything about the container being a bag, the term "bag" only appears in the preamble and the body of the applicant's claim specify nothing about the formed product being a bag (however, see alternate rejection below).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 19-22, 56, 57, 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heck (USP 4,428,743) in view of Sneider (USP 4,591,357) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

9. Upon advice of the appeal conferees in preparation for any future appeal, this rejection is a modification of the previous rejection relying on Heck and Sneider, where the order of the primary and secondary teachings is now reversed. Heck discloses a method for forming medical containers that comprises utilizing a vacuum mold that possesses the half the shape of the desired container Heck, which can be removed from the mold such that an additional sheet (i.e. the other half of the shape) can be utilized for the closing of the recess (col. 2, lines 29-39). Heck does not explicitly teach the use of a mold having the claimed planar wall, radiused periphery and a peripheral ledge. Sneider teaches in an alternate medical container that has a shape possessing the claimed planar wall, radiused periphery and a peripheral ledge. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the construction of Sneider (which would inherently require the use of a mold having

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the claimed planar wall, radiused periphery and a peripheral ledge) because the prior art recognized that vacuum molding is a conventional means for constructing medical containers.

10. Evidentiary teaching Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been further obvious to one of ordinary skill in the art at the time the invention was being made to utilize the method of Heck for the construction of the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Sneider discloses a plurality of portals (fig. 1 and 2) and the teaching of Sneider in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. The container of Sneider is disclosed as utilized for medicines requiring dilution and medicines can include thermolabile or biological substances. Portal 16 would be closed during mixing.

11. Claims 60 and 63 in the alternative are rejected under 35 U.S.C. 103(a) as being unpatentable over Medwed in view of Weiler et al (USP 4,176,153).

12. Claims 60 and 63 were anticipated by the teaching of Medwed both because these claims did not specify anything about bags in the body of the claim and because it is unclear to the examiner how the container of Medwed reads away from the term "bag" as the applicant has defined it (see rejection above as well as the arguments below). However, even if the examiner were to interpret these claims as both specifying bags in the body of the claims *and* reading the applicant defined term "bag" away from the container of Medwed, it is well known that a given

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molding method can find utility to construct a number of different but analogous articles. This is demonstrated by Weiler, which teaches that both containers (like those of Medwed) and bags are all analogous structures that can be constructed with a given molding method (col. 1, lines 9-15). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the method of Medwed for the construction of bags as taught by Weiler in order to increase the utility for a given mold to include other analogous structures.

Allowable Subject Matter

13. Claims 58 and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
14. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not disclose nor render obvious all the limitations of claims 56 or 57 and further comprising the step of freezing the bag.

Response to Arguments

15. Applicant's arguments concerning the outstanding 112 rejections were persuasive and the examiner has withdrawn these rejections. The examiner has also withdrawn the rejections utilizing Falk because Falk is not drawn to a container already possessing a circumferential flashing. Applicant's remaining arguments are either not persuasive or moot in view of the reorganization of the above rejections as suggested to the examiner by the appeal conferees.

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16. With respect to the rejection over Medwed, applicant urges that Medwed is not drawn to a bag. First, the examiner would point out that the body of the claim specifies nothing about the forming of a bag. Second, it is unclear to the examiner from the applicant's disclosure how the applicant's defined bag reads away from the container of Medwed. In particular, applicant teaches a container having shape memory and refers to said container as being a "bag". It is unclear from the specification when a container in the art having shape memory (e.g. Medwed) would cease to be considered by the applicant to be a "bag". Is it the degree of flexibility of the formed bag that keeps any flexible container from reading on "bag"? Is it because containers like the instant invention have been traditionally coined as "bags" in the medical art whereas other arts would not have referred to those same containers as "bags"? Applicant has never sufficiently addressed this issue and has merely argued that this container is not a bag.

17. With respect to the arguments concerning the combination of Sneider and Heck, applicant urges that the teaching of Sneider would not have looked to the teaching of Heck because they are two completely different containers. However, the point of the teaching of Heck was that the vacuum molding of half containers and forming a container out of two halves was conventional in the medical container art regardless of whether the final container is a bag or not (just like blow molding is conventional in the art for both containers and bags). There is nothing in col. 2, lines 29-39 of Heck that somehow limits this paragraph to the particular structure of Heck. In fact this passage of Heck is stating very conventional means for the formation of medical containers. It doesn't appear that the applicant has ever argued that vacuum molding containers halves (whether they are "bags" or not) was not known in the art at the time of the invention. If conventional means for container construction are not applicable to

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to the art of Sneider, then how would one possessing ordinary skill in the art construct the container of Sneider? Because Sneider does not specify any particular means for constructing the container, one possessing ordinary skill in the art would look to conventional means for constructing said container. Heck outlines said conventional means.

18. Applicant also relies on the fact that a container by Baxter cannot make fracture resistant containers. The examiner fails to understand the purpose of this analogy. First, the examiner never alleged that it would have been obvious to one of ordinary skill in the art to construct the bags of Baxter in any particular way. The claims are currently drawn to the formation of broadly defined bags and are in no way limited merely to the specific art that Baxter deals with. The fact that the claims reads far more broadly than on the mere formation of bags like those of the specific art of Baxter is the basis for the rejection. Second, it is the examiner understanding that the applicant's improvement over the prior art (which presumably includes the art of Baxter) was in large part due to the specified shape of the bag that dissipates forces engendered during freezing. However, Sneider taught said shape of bag and hence would inherently possess fracture resistance.

19. Applicant appears to argue that because the rejections in question utilizes optional evidentiary teachings, this somehow infers deficiency in the rejection of record. However, the examiner is puzzled that the applicant's representative is not more familiar with this well established and utilized principle of alternative rejections. In the instant case, the evidentiary teachings provide further motivation for the combinations in question. In many instances, there are numerous reasons for combining two elements of the prior art. The motivation may come from the references themselves or it may come from knowledge generally available to one

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possessing ordinary skill in the art (e.g. evidentiary teachings). Can the examiner not provide additional motivation without having that additional motivation imply that the original motivation provided is somehow deficient?

20. Applicant also urges that Sneider doesn't retain its shape. This is contradicted by col. 3, line 53 as well as by figure 2, which shows the device retaining its shape even though it is only partially filled with fluid. Applicant also urges that Sneider does not give details concerning the seamed edge. This is contradicted by col. 6, line lines 10-30, which discusses the sealing of the rib portion (i.e. the seam about the bag). In addition, the point of Heck is that the vacuum molding of Sneider would result in a seamed edge.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number form after-final communications is (703) 305-5408.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Kaj K. Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Patent Examiner
AU 1753
August 11, 2003